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TITLE: **Development of a PTSD Population Registry**

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Fort Detrick, Maryland 21702-5012

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14. ABSTRACT
The purpose of this project is to develop the first longitudinal registry of combat-exposed men and women with PTSD. This registry will provide essential data on the natural history and outcomes associated with PTSD in military service men and women who have utilized the Department of Veterans Affairs (VA) health care system. An additional goal of this project is to determine risk factors for PTSD among combat-exposed service men and women. There are no findings to report at this time as the project protocol was recently approved by OHRP on August 8, 2009. Now that OHRP and all site IRB approvals have been obtained, the pilot phase is slated to begin in September 2009.

15. SUBJECT TERMS
Risk factors for PTSD. PTSD symptom development and VA healthcare utilization.

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INTRODUCTION

The purpose of this project is to develop the first longitudinal registry of combat-exposed men and women with PTSD. This registry will provide essential data on the natural history and outcomes associated with PTSD in military service men and women who have utilized the Department of Veterans Affairs (VA) health care system. An additional goal of this project is to determine risk factors for PTSD among combat-exposed service men and women (by incorporating a combat-exposed non-PTSD group of veterans into analyses). Thus, the registry will allow an evaluation of current theoretical models of symptom development in a large sample of service men and women who utilize the VA medical system.

BODY

The first 10 months of year 1 were spent on an extensive review and revision of the study protocol and study aims. The doctoral level project coordinator and the research assistant were hired and trained in month 1. The study's Scientific Advisory Board met in month 1 to provide feedback on the initial protocol and study measures. The feedback received at the SAB meeting and from the initial OHRP review (August 2008) served at the basis for the revisions made to the study protocol and study aims. Additionally, the statistical analysis and data de-identification plans were finalized in months 2 through 6. In months 7 and 8 the primary method of data collection was changed from paper and pencil mailing to online data collection in order to make participation in the study more convenient for subjects. The online data collection protocol was developed and a vendor was identified. A standardized safety plan was also added to the protocol during month 8 to provide assessors with a clear plan of action should an adverse event occur during a phone assessment.

As revisions were made to the study protocol, changes were submitted to the Institutional Review Boards of the New England Research Institute (NERI), VA Boston Healthcare System, and The Washington DC VA Medical Center, for approval on an ongoing basis during months 4 through 10. Waivers of HIPAA authorization and documentation of informed consent were obtained at the VA Boston Health Care System and Washington DC VA Medical Center. The finalized versions of the study protocol, study materials, and all study site IRB approvals were submitted to OHRP in month 11 and final OHRP approval was obtained in month 12.

In month 9 the budget was restructured to reflect the additional technological and personnel needs necessitated by delayed start of the project due to the protocol review/revision and approval process. A revised statement of work accounting for the extended protocol revision and approval process was also submitted for review during month 9. Funds were allotted for an additional masters-level clinical interviewer as well as an additional research technician to help meet the project timeline described in the amended SOW. After the rebudget request was approved in month 10, the additional research technician was hired and we began interviewing for the masters level clinical interviewer position. In months 10 through 12 the necessary IT

equipment and access to the web-based program for online data collection, PsychData, was purchased. To date there have not been any problems that have impeded performance of the project.

Personnel receiving salary from this research effort are Darren Holowka, PhD (project coordinator and clinical interviewer) and Joseph Gonzalez (research technician). Elise Ratchford (research technician) and Daniella Halperin M.A. (clinical interviewer) will be hired in months 1 and 2 (of Year 2), respectively, and will receive a salary.

KEY RESEARCH ACCOMPLISHMENTS

- All relevant approvals obtained for revised protocol
- Registry database programmed
- Online data collection platform programmed. Error testing of online Project VALOR questionnaire completed.

REPORTABLE OUTCOMES

- Keane, T.M., Rosen, R., Maserejian, N., Holowka, D.W., Rodriguez, P., Marx, B.P., Kang, H., Vasterling, J.J. Wunderle, K.B., Rodier, N.A., Sloan D.S., Friedman, M.J., Sleeper, L.A. (2009). Creation of a PTSD Registry for Veterans: Project VALOR. Poster to be presented at the annual meeting of the Association for Behavioral and Cognitive Therapies, New York, NY (November 19-22, 2009).

- Keane, T.M., Rosen, R., Maserejian, N., Holowka, D.W., Rodriguez, P., Marx, B.P., Kang, H., Vasterling, J.J. Wunderle, K.B., Rodier, N.A., Sloan D.S., Friedman, M.J., Sleeper, L.A. (2009). Creation of a PTSD Registry for Veterans: Project VALOR. Poster and oral presentation at the Department of Defense (DOD) Military Health Research Forum (MHRF); Kansas City, MO.

CONCLUSION

The PTSD registry will provide information to assist researchers, military leaders, and treatment providers to better understand the etiology and course of PTSD, how it can be identified at early stages, and the responsiveness of recent returnees to various treatment options. This knowledge will be of benefit to policy makers and current service members as well as victims of trauma in the broader community. It will include:

- Evaluation of the natural history and long-term outcomes of PTSD across treatments, treatment settings, and practitioners, using cost-efficient methods and economies of scale;
- A more accurate assessment of current theoretical models of symptom development, and

- Documentation of health resource utilization and development of a database that is an ideal resource for health services planning and policy.

Furthermore, this study will contribute:

- The formation of a potential cohort of subjects for ancillary studies, ranging from genomic influences to quality of life and psychosocial outcomes, as well as future clinical trials;
- The creation of a representative sample of PTSD OEF/OIF Veterans who use the VA medical system, available for use in epidemiologic studies, particularly for comparisons with active duty and other Veteran or civilian populations;
- Utility to clinicians, patient advocacy groups, and health policy planners;
- Publications and dissemination of the registry results to provide a representative perspective of what is achieved in actual current care settings, thereby augmenting outcomes data from clinical trials.

APPENDIX

AMENDED STATEMENT OF WORK – MAY 12, 2009

START DATE- September 1, 2008

VA Boston Healthcare System (BVARI)
Research Service (151)
150 South Huntington Avenue
Boston, MA 02130
PI: Terence M. Keane, Ph.D.

New England Research Institutes, Inc. (NERI)
9 Galen Street
Watertown MA 02472
Partnering PI: Raymond Rosen, Ph.D.

This project requires human subject participation.

Major Task (Milestone)	Timeline (Months)	BVARI	NERI
PHASE I – STUDY INITIATION			
IRB Approvals/Finalize Protocol			
Finalize Protocol; NERI/VHA IRB approvals and USAMRMC HRPO human subject protocol approval	1-11 TK	/BM	RR
Program and Test De-Identification			
Programs to de-identify VA in/outpatient electronic records database will be created	1-4 TK/BM		RR
De-Identification programs will be tested on sample data	1-6 TK/BM		RR
Design statistical analysis programs	3-6 TK/BM		RR
PHASE II – DATA COLLECTION			
Prepare Data for Abstraction			
Data on potential participants will be merged from electronic databases	11-27 TK/	BM	
Data will be de-identified	12-27 TK/	BM	
Transfer Data	26-27 TK/BM		RR
Resolve Queries			
Generate query reports that relate to the quality of the database based on pre-determined values	9-10		RR
Data cleaning and tracking	11-27		RR
Pretest telephone Interview Instrument			
The interview will be tested in a sample of 20 veterans who will not be enrolled in the study to assess burden, ease of comprehension and time to completion	12-13 TK/	BM	
Make modification based on pre-testing	12-13 TK/BM		RR
Final interview tested to allow completion in a 40-50 minute telephone call	12-13 TK/	BM	
Develop manual of operations	10-13 TK/BM		RR

Identify Target Sample for Interview			
Identify 1200 OIF/OEF veterans with diagnosis of PTSD, 400 OIF/OEF veterans without diagnosis of PTSD and a mental health evaluation/assessment conducted post-deployment years in the VA medical records database	11-12 TK/	BM	
Conduct Interim Analyses			
Conduct interim analyses using existing PTSD Registry data	14-15		RR
Conduct Interviews			
Interviewers will be extensively trained and monitored for quality assurance	10-26 TK/BM		RR
Patients will be contacted by telephone to conduct informed consent.	12-26 TK/	BM	
Patients who provide their consent will complete the interview	13-26 TK/	BM	
Interview Data Entry De-Identification and Transfer			
Data entry and quality control measures will be ongoing at the VA	12-27 TK/	BM	
Data will be de-identified	13-27 TK/	BM	
Data will be transferred to NERI	26-27		RR
PHASE III – DATA ANALYSIS & REPORTS			
Conduct Data Analysis			
Analyses will be conducted to address the Specific Aims of the Registry	24-36		RR
Reports and Publication	24-36 TK/BM		RR
Continued Abstraction of Medical Records			
Perform abstraction periodically of VA in/outpatient electronic medical records for PTSD registrants who have return in/outpatient visits to VA medical centers	24-36 TK/BM		RR
Prepare PTSD Database for Future Use			
PTSD Registry database of 1200 OIF/OEF veterans will be prepared for potential sharing as a public dataset	34-36 TK/BM		RR